K110550

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510(k) Summary

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Proprietary Name: Bright Embrace Model SBL60

Common Name: Neonatal Phototherapy Light

Classification Name: Unit, Neonatal Phototherapy

Regulation number: 21 CFR 880.5700

Classification: Class II

Product Code: LBI

Predicate Device: Physician Engineered Products, Inc. – Ultra Bili Light (K974830)

Device Description:
The Bright Embrace Model SBL60 is a single-patient, portable phototherapy light that was specifically designed to incorporate these features:

1) high intensity blue light over a large body surface area – as recommended by the American Academy of Pediatrics (AAP);
2) the ability to hold the newborn during treatment;
3) single patient use to minimize cross-contamination in hospitals and to facilitate home care logistics;

The Bright Embrace Model SBL60 delivers a narrow band of high-intensity blue light via blue light emitting diodes (LEDs) to provide treatment for neonatal hyperbilirubinemia, also called newborn jaundice. The Bright Embrace Model SBL60 is designed to provide phototherapy treatment from a wrap-around design that provides light from underneath, the sides and partially the front of the newborn to achieve a large body surface area of treatment.

The blue LEDs used in the Bright Embrace Model SBL60 emit light in the range of 430-510nm (peak wavelength 480nm). This range corresponds to the spectral absorption of light by bilirubin, and is thus considered to be the most effective for the desirable degradation of bilirubin under the exposed skin. Blue LEDs do not emit significant energy in the ultraviolet (UV) region of the spectrum, so there is no concern about UV exposure to the newborn. As with most phototherapy devices, protective eye shades or goggles must be used to protect the newborn's eyes from excessive light exposure.

Since LEDs have minimal light output degradation over 10,000 hours (with proper use), and since the Bright Embrace Model SBL60 is designed for single patient use of 60 hours of phototherapy or less, there is no significant degradation of light output over the life-span of the Bright Embrace Model SBL60.

The irradiance by the Bright Embrace Model SBL60 to the newborn's skin averages 38 $\mu W/cm^2/nm$ – nicely in the range for "intense phototherapy" recommended by the AAP of >30 $\mu W/cm^2/nm$. The body surface area (BSA) treated by these lights covers 501 cm^2, or 21% of the BSA of an average size newborn – consistent with the AAP recommendation to treat "as much body surface area as possible."

A newborn being treated in a Bright Embrace Model SBL60 can be held for feeding or cuddling during treatment. Otherwise, it is recommended that the Bright Embrace Model SBL60 and newborn be placed in a crib or bassinette or on a warming table or in an incubator for security.

The single-patient design of the Bright Embrace Model SBL60 virtually eliminates the risk of cross-contamination between newborns. The newborn is swaddled in a light-transmitting, disposable non-woven spun-bound material "Softy" for comfort and cleanliness. The baby and Softy swaddling overlie a clear PVC (nonreactive) plastic tray that overlies the LEDs and the electronic circuitry including an hour meter. The back of the device is soft, flexible, non-absorbent neoprene.

60 hours was determined to be an appropriate maximum for this single use device. Based on non-published PEP outcome studies with the similar-dose device, the PEP Ultra Bili Light, over 95% of newborns requiring phototherapy need less than 60 hours. After searching medical publications and literature available from other phototherapy device manufacturers, no other treatment times data could be found or is known.

The hour meter timing control built into the Bright Embrace Model SBL60 is simply a LCD display that shows the hours left on the machine. It is set at manufacture to 60 hours and counts backward when the unit is on until phototherapy is completed or until the timing control reaches zero hours, at which point the unit will no longer light. It's purpose is to ensure the single-patient intent of the device; it does not control or determine the treatment time of the newborn. The simple timer programming circuitry contains minimal software.

The Bright Embrace Model SBL60 system consists of 4 components: the light source, the low-voltage power supply, disposable "Softy" swaddling material, and Bili-Goggles (or other eye protection). In addition, there are included instructions for use and a mail-back box for green recycling.

Intended Use:
The Bright Embrace Model SBL60 phototherapy light is intended for the treatment of neonatal hyperbilirubinemia. It is designed to provide phototherapy treatment from underneath and around the newborn. The Bright Embrace Model SBL60 can be used in a clinical setting or in the home.

Comparison with Predicate Devices:
The Bright Embrace Model SBL60 and the Ultra Bili Light have the same intended use of treatment of neonatal hyperbilirubinemia and use the same operating principle of delivering bright blue light to degrade bilirubin. The Ultra Bili Light is chosen as a predicate because: 1) it is PEP's other neonatal phototherapy device; 2) it provides "intense phototherapy" (as defined by the AAP) to a large body surface area – as does the Bright Embrace Model SBL60. See the Comparison Table below for details:

Device Comparison Table **Feature:**	**PEP Bright Embrace Model SBL60**	**PEP Ultra Bili Light (K974830)**
Intended Use	For treatment of neonatal hyperbilirubinemia	For treatment of neonatal hyperbilirubinemia
Treatment Method	Around newborn phototherapy	Overhead and side of newborn phototherapy
Target Population	Neonates	Neonates
Sites of Use	Clinical setting, home-use	Clinical setting, home-use
Specifications:		
Type of Device	Free standing device	Free standing device
Type of Light	Blue light LED	Blue light fluorescent
Intensity average	38 μW/cm²/nm	60 μW/cm²/nm
Dimensions	43cm long x 48cm wide x 5cm high	46cm long x 58cm wide x 46cm high
Weight	0.55 kg (1.2 lb)	6.5 kg (14 lb)
Treatment area as % of newborn body surface area (BSA)	501 cm² - 21% of BSA	960 cm² - 40% of BSA
Phototherapy Treatment Units (PTUs) = irradiance x BSA	38 μW/cm²/nm x 21% BSA = 800 PTUs	60 μW/cm²/nm x 40% BSA = 2400 PTUs
Materials:		
Device	PVC enclosure with neoprene back	Polyethylene case
Mattress	na	Vinyl covered foam cushion
Patient contact	Nonwoven spunlaced polyester fabric	Nonwoven spunlaced polyester pad
Miscellaneous:		
Shape	Tubular around newborn	Rectangular suitcase style
Portable	Yes	Yes
Use Intent	Single-Patient	Multi-Patient
Duration of Treatment	Expect under 60 hours	28 hr. average, 95% < 60 hrs.
Standards and Safety:		
Electrical Safety – Power Supply: Device:	 UL60601-1-3, CUL to 22.2#601, DEMKO to EN60601, CE Class II, PSE to J60950, CB Report, VCCI, EN 60601-1-2:2001, EN61000-3-2, EN61000-3-3 & EN50082-1, including EN61000-4-2, EN61000-4-3, EN61000-4-4, EN61000-4-5, EN61000-4-6, EN61000-4-11, Level 4 IEC 60601-1	na
Electromagnetic Conduction:	IEC 60601-1-2	na
Infant (sic) Phototherapy Equipment Safety	IEC 60601-2-50	na

Mechanical Safety	Padded wrap-around design holds newborn – fits inside crib or bassinet. Bili-Goggles protect newborns' eyes.	Built-in tray holds newborn. Fits inside crib, not bassinet. Face shield or Bili-Goggles protect newborns' eyes.
Thermal Safety	Fluted design dissipates LED heat.	Heating pad under newborn if device below 21°C. Thermal protection circuit turns off bulbs of device gets too warm.
Radiation safety	LED light source emits no UV light.	UV-blocking plastic sheet covers fluorescent bulbs
Human Factors:		
Controls and Indicators	On-Off jack; Hours meter counts back from 60 hours – a LCD digital display located at the base of the device and visible between the newborns' legs. Device turns off when hour meter reaches zero.	On-Off switch, Hour meter, low/high temperature indicator lights, 2000 hour bulb change indicator
Compatibility with environment, other devices	Used inside bassinet, crib, warmer table, incubator	Used inside crib or on specialized hospital cart

Specifications:

Type CF applied parts

Light source: blue LED bulbs – Hebei 540LB7C

126 high-intensity blue LED bulbs provide phototherapy of the desired color –

1. 430-510nm color range
2. peak at 480nm

Power supply: Use only power supply provided – Glob-Tek Model GTM41060-2515:

In:

1. Voltage: ∿ 100-240 VAC wall power supply with connecting jack
2. Amps: 0.8A
3. Freq.: 50Hz/60Hz

Out:

1. Voltage: ⎓ 15.0 VDC output to Bright Embrace
2. Amps: 1.8A max.

6-foot cord

Hour meter - LCD panel displays phototherapy hours – counting back from 60 hours to zero when unit is on. At zero hours the unit's lights will no longer come on.

Dimensions: 43 cm long x
48 cm wide x
5 cm high

Weight: 0.55 kg (1.2 lb)

Environmental Limits:

Storage Limits:

Temperature: low limit = -5°C (23°F); high limit = 49°C (120°F)

Humidity: < 90 %rh

Use Limits:

Temperature: low limit = 18°C (65°F); high limit = 35°C (95°F)

Humidity: < 90 %rh

Handling


Keep Dry

Handle with Care

Risk of Disposal – LEDs bulbs may contain toxic materials. Recycle as instructed.

The Bright Embrace Model SBL60 contains instructions to the user, a return mailing container and a financial incentive to return the device to Physician Engineered Products for recycling.

Mechanical Safety: Padded wrap-around design holds newborn – fits inside crib or bassinet. Bili-Goggles protect newborns' eyes.

Thermal Safety:

Fluted design dissipates LED heat. No cooling required.

Radiation Safety:

Blue LED light source emits no UV light.

Nonclinical Testing:

A. Standards Testing:

A.1. IEC 60601-1: 2005 – This Medical Electrical Equipment Safety standard testing was completed on the Bright Embrace Model SBL60 power supply – the GlobTek Model GTM41060-2515, Switching Power Supply - by SIQ, a certified CB Testing Laboratory. The 244 page report attached (see Attachment A.) confirms that the Bright Embrace Model SBL60 power supply meets this standard as well as the related standards as listed in the comparison chart above:
UL60601-1-3,
CUL to 22.2#601,
DEMKO to EN60601,
CE Class II, PSE to J60950, CB Report, VCCI,
EN 60601-1-2:2001, EN61000-3-2, EN61000-3-3 & EN50082-1, including EN61000-4-2, EN61000-4-3, EN61000-4-4, EN61000-4-5, EN61000-4-6, EN61000-4-11

The entire device underwent this standard testing by Intertek. The report is included as Attachment A-2.

A.2. IEC 60601-1-2: 2004 – This Electromagnetic Conduction Safety standard testing was completed on the Bright Embrace Model SBL60 device by Intertek, a certified standards testing laboratory. The report conclusions included below confirms that the Bright Embrace Model SBL60 meets this standard. The full, 55-page text of this report may be found in Attachment B.

Electromagnetic Conduction (EMC) Safety: IEC 60601-1-2:2004

Guidance and Manufacturer's Declaration – Emissions – All Equip. & Systems

The SBL60 is intended for use in the electromagnetic environment specified below. The customer or user of the SBL60 should ensure that it is used in such an environ.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The SBL60 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electrical equipment.
RF Emissions CISPR 11	Group 2	The SBL60 must emit Electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	
		The SBL60 is suitable for use in all buildings, other than domestic directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Immunity – All Equip. & Systems

The SBL60 is intended for use in the electromagnetic environment specified below. The customer or user of the SBL60 should ensure that it is used in such an environ.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance

ESD EN/IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT EN/IEC 61000-4-4	±1kV Mains	±1kV Mains	Mains power quality should be at least that of a typical commercial or hospital environment:
Surge EN/IEC 61000-4-5	±kV Differential	±kV Differential	Mains power quality should be at least that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/EIC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be at least that of a typical commercial or hospital environment. If the user of the SBL60 requires continued operation during power mains interruptions, it is recommended that the SBL60 be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz Magnetic Field EN/IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Emissions – Equipment and Systems that are <u>NOT Life-Supporting</u>

The SBL60 is intended for use in the electromagnetic environment specified below. The customer or user of the SBL60 should ensure that it is used in such an environ.

Immunity Test	EN/IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from the SBL60 by no less than the distances calculated/listed below:
Conducted RF EN/IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	(3) Vrms	D=(3.5/V1)(Sqrt P)
Radiated RF EN/IEC 61000-4-	3V/m 80 MHz to 2.5	(3) V/m	D=(3.5/V1)(Sqrt P) 80 to 800 MHz

3	GHz		D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Fields strength from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1) Interference may occur in the vicinity of equipment containing a transmitter.

Recommended Separations Distances for the SBL60 - Equipment and Systems that are NOT Life-Supporting

The SBL60 is intended for use in the electromagnetic environment in which the radiated disturbances are controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the SBL60 as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)	Separation (m) 80 to 800 MHz D=(3.5/E1)(Sqrt P)	Separation (m) 800MHz to 2.5Ghz D=(7/E1)(Sqrt P)
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

- Radiation Safety: IEC 60601-1-2:2004; LED light source emits no UV light

A.3. IEC 60601-2-50: 2000/07/01 Ed:1 – Particular Requirements for the Safety of Infant (sic) Phototherapy Equipment. This Safety standard testing was completed on the Bright Embrace Model SBL60 device by Intertek, a certified standards testing laboratory. See Attachment A-3.

B. Tests Performed at Physician Engineered Products, Inc.:
B.1. Irradiance test:

Lab Test Form

Product:_____Bright Embrace Model SBL60_____ Date: _6/10/11_____

Irradiance test of Bright Embrace Model SBL60

Reason for Test (explain in detail):
The Bright Embrace prototype Model SBL60 is tested for blue light irradiance to determine if:
1) it meets the American Academy of Pediatrics recommended level for "intense phototherapy" – over 30 μW/cm²/nm;
2) it meets the IEC 60601-2-50 light distribution standard of *Ebi min / Ebi max* > 0.4

Test Performed:
1) A Bright Embrace prototype Model SBL60 is tested using a newly calibrated Natus neoBLUE LED Phototherapy radiometer;
2) The device is turned on and wrapped into the normal use position (as if wrapped around a newborn receiving phototherapy);
3) The sensor head of the light meter is placed against the clear plastic inner surface of the device and aimed at the light source – simulating the light as it would hit the newborn's skin;
4) 30 measurements are taken from 10 adjacent LED "spotlights" (in a 2 x 5 grid) – representing 8% of the 126 LED "spotlights". The 2.25 cm. diameter "spotlights" are divided into 3 concentric rings – each ring with a width of 0.375 cm – Ring 1 from 0-0.375 cm from center; Ring 2 from 0.375-0.75 cm from center; Ring 3 from 0.75-1.125 cm from center. Irradiance measurements are taken at points 0 cm., 0.5 cm., and 1.0 cm. from the center of the "spotlights" to accurately represent irradiance readings in each ring. The average irradiance, the minimum (*E*bi min), and the maximum (*E*bi max) irradiances, and the distribution (*Ebi min / Ebi max)* are determined;

Test Results: Irradiance (μW/cm²/nm) Area (cm²)

"Spotlight":	1	2	3	4	5	6	7	8	9	10	Avg		%
Ring 1:	57	56	55	56	56	54	56	52	57	55	55.4	0.44	11
Ring 2:	50	45	54	45	48	48	50	44	53	49	48.6	1.16	29
Ring 3:	33	29	35	29	29	29	32	26	33	28	30.3	2.38	60
Total												3.98	100

Calculate:	Avg. irradiance		x % of "spotlight"		= share of irradiance
Ring 1:	55.4	x	.11	=	6.09
Ring 2:	48.6	x	.29	=	14.09
Ring 3:	30.3	x	.60	=	18.18
Total Average Irradiance:					**38.36 μW/cm²/nm**

Total BSA: **3.98 cm²/"spotlight" x 126 "spotlights" = 501 cm²**
% BSA: **501 cm² / 1800 cm² (average newborn BSA) = 28% BSA**

1) Average irradiance: **38 μW/cm²/nm**

2) Range of irradiance: *Ebi min* = 26 μW/cm²/nm to
Ebi max = 57 μW/cm²/nm

3) Distribution: *Ebi min / Ebi max* = 26 / 57 = 0.46

Pass / Fail criteria:

1) Irradiance average at or over 30μW/cm²/nm;

2) Distribution: >0.4

Conclusions:

1) The average irradiance of the Bright Embrace Model SBL 60 meets the AAP guidelines for "intense phototherapy";

2) The phototherapy light distribution of the Bright Embrace Model SBL 60 meets the IEC 60601-2-50 light distribution standard.

B.2. Body Surface Area (BSA) test:

Lab Test Form

Product:_____Bright Embrace Model SBL60_____ Date: ___1/10/2011___

Reason for Test (explain in detail):
The purpose of this test is to determine what newborn body surface area (BSA) is treated with phototherapy by the Bright Embrace Model SBL60. The AAP recommends "intense phototherapy" to "as much BSA as possible". Therefore, it is important to determine what % BSA is being treated by the Bright Embrace Model SBL60.

Test Performed:
A term-sized neonatal manikin is wrapped inside the Bright Embrace prototype Model SBL60 and the unit turned on. Areas of the body parts of the manikin – head, neck, trunk, arms, legs, genital area – that are visibly lit by the blue light "spotlights" of the 126 LED bulbs in the Bright Embrace are recorded. The area or each spotlight that hits the manikin is then measured. By multiplying the # of spotlights x the surface area treated by each, a total BSA treated can be calculated. This area is then divided by the BSA of a standard newborn BSA (1800 cm^2) to determine what % of the total BSA is treated by the Bright Embrace Model SBL60.

The test was then repeated using a premature-sized infant (premie) manikin and the area is then divided by the BSA of a standard premie BSA (1to determine what % of the total BSA is treated by the Bright Embrace Model SBL60.

Test Results: Spotlight area: 2.25 cm diameter = 3.98 cm^2

	# LEDs lighting manikin	x 3.98 cm^2 = BSA treated
Normal manikin:	126	x 3.98 cm^2 = 501 cm^2
Premie manikin:	120	x 3.98 cm^2 = 478 cm^2

Calculate: normal-size newborn % BSA treated: 501 cm^2 / 1800 cm^2 = 28%
Total % BSA of normal-size newborn treated by the Bright Embrace = **28%**

premie-size newborn % BSA treated: 478 cm^2 / 1300 cm^2 = 37%
Total % BSA of premie-size newborn treated by the Bright Embrace = **37%**

Pass / Fail criteria: > 20% BSA desirable

Conclusions:
1) The Bright Embrace Model SBL60 provides treatment to the desirable BSA of an average term newborn;
2) The Bright Embrace Model SBL60 provides treatment to the desirable BSA of an average premature newborn.

B.3. Temperature test:

Lab Test Form

Product:_____Bright Embrace Model SBL60_____ Date: ___2/10/2010___

Operating Temperature Test:

Reason for Test (explain in detail):
The LED light source in the Bright Embrace Model SBL60 generates some heat. This test is to determine that the heat generated by the device is in an acceptable, safe range – i.e., that it meets the IEC 60601-2-50 standard of not exceeding 40°C at any location that touches the newborn.

Test Performed:
1) A Bright Embrace prototype Model SBL60 is tested using an Omega Model 450 digital thermometer using the air sensor;
2) The device with and without a Softy attached is turned on and rolled into the tubular position of normal use – as if wrapped around a newborn;
3) The temperature sensor is placed directly over an LED "spotlight" on the Bright Embrace Model SBL60 in 12 locations: at the left, back and right sides at mid-head, mid-chest, mid-abdomen and knee levels;
4) Allowing 120 minutes at each location for equilibration, the temperature is measured and recorded.

Test Results:

	°C – air / surface	
Site:	**With Softy**	**Without Softy**
left ear	30.0 / 25.0	23.5 / 26.6
occiput	25.8 / 24.9	23.9 / 26.5
right ear	28.1 / 24.8	25.3 / 26.8
left chest	29.4 / 29.3	29.7 / 31.6
back chest	30.5 / 32.8	30.0 / 31.5
right chest	27.8 / 26.5	28.6 / 31.1
left abdomen	28.1 / 30.1	30.1 / 31.2
back abdomen	31.7 / 31.9	29.3 / 29.3
right abdomen	27.1 / 29.4	28.9 / 30.3
left side knee	24.9 / 26.3	27.3 / 28.9
back of knee	23.2 / 24.8	26.8 / 27.5
right side knee	26.9 / 26.1	28.3 / 29.9
Average	27.8 / 27.7	27.6 / 29.3
Ambient	22.2 / 22.1	22.7 / 23.4
Maximum	**31.7 / 31.9**	**30.1 / 31.2**

Pass / Fail criteria: no location > 40°C.

Conclusions:
1) Average temperature of 27-29 °C (81-84°F) is in the acceptable range for unclad babies.
2) No temperatures exceeded the 40 °C (104°F) limit – the 60601-2-50 standard is met.
3) The thermal environment inside the Bright Embrace Model SBL 60 is safe.

B.4. Environmental Temperature/Humidity test:
Lab Test Form

Product:_____Bright Embrace Model SBL60_____ Date: ___5/12/2010___

Storage Temperature Test

Reason for Test (explain in detail):
The Bright Embrace Model SBL60 may be stored under a variety of environmental circumstances. The power supply - Glob-Tek Model GTM41060-2515 - is rated to these environmental storage limits:

- Temperature: low limit = -5°C (23°F); high limit = 60°C (140°F);
Humidity: 0-90% rH

The purpose of this test is to determine if these limits are appropriate for the entire Bright Embrace Model SBL60 device.

Test Performed:
1) Two Bright Embrace Model SBL60 prototype devices – including: the light source, the power supply, the Softy and the Bili-Goggles are placed in 2 temperature-controlled containers – one freezer set to -5°C (23°F) and one incubator set to 60°C (140°F) – both at 90% rH - for 60 days each.
2) After the 60 days, the 2 devices are tested for:
    defects - by visual observation of all four components:
        - the light source after folding and unfolding the device into the wrapped position 10 times;
        - the power supply by visual check of cord and supply;
        - the Softy, and
        - the Bili-Goggles
    function – turning on and off the device 10 times, and
        - measuring the irradiance at zero hours and 4 hours.

Test Results:
1) Neither of the two Bright Embrace Model SBL60 prototype devices revealed any visual defects after 10 foldings and unfoldings. The power supply, Softy and Bili-Goggles appeared undamaged.
2) The devices turned on and off 10 times each without failure;
3) The irradiance readings at 0 hours and 4 hours are the same as prior to storage.

Conclusion:
1) The Environmental Storage Temperature Limits specified by the power supply - Glob-Tek Model GTM41060-2515 – are appropriate for the entire Bright Embrace Model SBL60 device.

B.5. Leakage test:

Lab Test Form

Product:_____Bright Embrace SBL60_____Date: __7/29/2010____

Title: SBL60 Leakage Test

Reason for Test (explain in detail):
Leakage testing is needed to determine the appropriate medical device applied parts Type – B or BF or CF

Test Performed:
An SBL60 working prototype is tested with a BC Biomedical SA-2000 Safety Analyzer in all configurations and the µAmps or ohms are recorded. These readings are then compared to the leakage requirements for the applied parts Type B, BF and CF standards.

Test Results:

	Hot:	Neutral:	Ground:	Polarity:	**µA:**
Enclosure:	closed	closed	closed	FWD	000
	closed	closed	closed	REV	000
	open	closed	closed	FWD	000
	open	closed	closed	REV	000
	closed	open	closed	FWD	000
	closed	open	closed	REV	000
	open	open	closed	FWD	000
	open	open	closed	REV	000
Earth/Ground:	closed	closed	open	FWD	000
	closed	closed	open	REV	000
	open	closed	open	FWD	000
	open	closed	open	REV	000
	closed	open	open	FWD	000
	closed	open	open	REV	000
	open	open	open	FWD	000
	open	open	open	REV	000

	Hot:	Neutral:	Ground:	Polarity:	Ω
Earth Resistance:	closed	closed	closed	FWD	1
	closed	closed	closed	REV	1
	open	closed	closed	FWD	1
	open	closed	closed	REV	1
	closed	open	closed	FWD	1
	closed	open	closed	REV	1
	open	open	closed	FWD	1
	open	open	closed	REV	1

Pass / Fail Criteria:

Applied Parts Type:		B	BF	CF	(normal/single fault)
(μA)	Enclosure:	100/500	100/500	100/500	
	Ground:	500/1000	500/1000	500/1000	
	Patient:	100/500	100/500	10/50	

Conclusions:

1) Leakage tests are all at 000 μA.
2) The SBL60 qualifies for applied parts Type CF.

Summary of Non-Clinical Testing:
The Medical Electrical Equipment Safety standard IEC 60601-1 for the power supply and the entire device is met.
The Electromagnetic Conductance (EMC) standard IEC 60601-1-2 for the device is met.
The Particular Requirements for the Safety of Infant (sic) Phototherapy Equipment standard IEC 60601-2-50 is met.
This submission includes the results of testing of prototype devices to specifications – including irradiance, BSA, temperature and environmental conditions, and leakage testing. The results were as expected, and no new issues of safety or effectiveness were raised as a result of this testing.

Clinical testing:
Since the treatment of neonatal hyperbilirubinemia with blue light phototherapy is a well-established clinical practice, clinical or animal testing to demonstrate safety and effectiveness is not necessary.

Conclusions:
Based on the data and the information presented in this submission, the Bright Embrace Model SBL60 has undergone and passed more standards testing than the predicate – ensuring the Bright Embrace Model SBL60 is at least as safe as the predicate. In addition, the irradiance and BSA tests document that the Bright Embrace Model SBL60 treatment light dose is substantially equivalent to the currently marketed predicate Ultra Bili Light light dose. Therefore, the Bright Embrace Model SBL60 is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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FEB - 3 2012

Re: K110550
Trade/Device Name: Bright Embrace Model SBL60
Regulation Number: 21 CFR 880.5700
Regulation Name: Neonatal Phototherapy Unit
Regulatory Class: II
Product Code: LBI
Dated: December 28, 2011
Received: January 10, 2012

Dear Dr. Rose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110550

Device Name: _____Bright Embrace Model SBL60_____

Indications for Use:

The Bright Embrace Model SBL60 phototherapy light is intended for the treatment of neonatal hyperbilirubinemia. It is designed to provide phototherapy treatment from underneath and around the neonate. The Bright Embrace can be used in a clinical setting or in the home.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110550